Claims listing:

1. (currently amended) An implantable device for controlling the internal circumference of an anatomic orifice or lumen, comprising:

an annular ring an implantable device with an adjustable member configured to adjust the dimensions of the implantable device, the implantable device configured to be coupled to a fastener means by which said annular ring can be fastened that provides fastening of said implantable device to the tissue around an the anatomic orifice or lumen;

means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference; and

an adjustment tool configured to actuate the adjustable member and provide for adjustment before, during or after the anatomic orifice or lumen resumes near normal to normal physiologic function; and

wherein the adjustable member is positioned off plane relative to the implantable device to provide that the implantable device can be adjusted on a beating heart to cause leaflet coaptation and positioned to enable attachment to and adjustment of the implantable device, and detachment from the implantable device and removal from the body under normal beating heart conditions.

means associated with said annular ring for maintaining said ring in said first circumference and, upon said annular ring being adjusted to said second circumference, for maintaining said annular ring in said second circumference;

whereby the circumference of said anatomic orifice or lumen can be adjusted by adjusting the circumference of said annular ring from said first circumference to said second circumference.

2. (currently amended) The implantable device of claim 1, <u>further comprising:</u>

wherein said <u>a fastening member</u> means by which said annular ring can be

fastened to the tissue around an anatomic orifice or lumen comprises <u>that includes</u> a

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plurality of barbs extending from said annular ring implantable device for engaging the tissue around said anatomic orifice or lumen.

- 3. (currently amended) The implantable device of claim 2, wherein each of said barbs is oriented in a consistent, tangential direction with respect to the annular ring such implantable device to provide that rotational motion of the annular ring implantable device in a first direction will engages said retention barbs with the desired tissue, and rotational motion of the annular ring implantable device in a direction opposite to said first direction will disengages said retention barbs from said desired tissue.
- 4. (currently amended) The implantable device of claim 3, wherein each of said barbs further comprises includes a hook at its free end.
- 5. (currently amended) The implantable device of claim 1, wherein said <u>fastener</u> member means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises <u>includes</u> an outer fabric sheath covering said annular ring <u>implantable device</u> through which sutures can be placed to suture said implantable device to said tissue around said anatomic orifice or lumen.
- 6. (currently amended) The implantable device of claim 1, wherein said <u>fastener</u> device means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises <u>includes</u> a plurality of grommets spaced around the periphery of said <u>annular ring</u> implantable device.
- 7. (currently amended) The implantable device of claim 6, wherein said sutures can be placed and then through the underlying tissue to anchor said annular ring implantable device to the tissue around said anatomic orifice or lumen.
- 8. (currently amended) The implantable device of claim 6, wherein said grommets are comprised made of a material which is sufficiently soft that a suture can be placed through said grommet and through the underlying tissue to anchor said

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annular ring implantable device to the tissue around said anatomic orifice or lumen.

- 9. (currently amended) The implantable device of claim 6, wherein said grommets comprise include tabs comprised of a material which is sufficiently soft that a suture can be placed through said tab and through the underlying tissue to anchor said annular ring implantable device to the tissue around said anatomic orifice or lumen.
- 10. (currently amended) The implantable device of claim 6, wherein said grommets comprise include tabs, and wherein said tabs that define holes through which a suture can be placed and then through the underlying tissue to anchor said annular ring implantable device to the tissue around said anatomic orifice or lumen.
- 11. (currently amended) The implantable device of claim 1, wherein said adjustment member means associated with said annular ring for permitting adjustment of the a circumference of said annular ring from a first-circumference to a second circumference comprises includes corrugations.
- 12. (currently amended) The implantable device of claim 6, wherein said implantable device comprises includes alternating sections of corrugations and grommets spaced around the periphery of said annular ring implantable device.
- 13. (currently amended) The implantable device of claim 1, wherein said annular ring implantable device comprises includes a hollow tube formed into an annular shape, said tube having interspaced smooth and corrugated sections disposed around its circumference, wherein said means by which said annular ring implantable device can be fastened to the tissue around an anatomic orifice or lumen comprises said tube being sufficiently soft such that a suture can be passed through said tube and hence through the underlying tissue; wherein said means associated with said annular ring implantable device for permitting adjustment of the circumference of said annular ring implantable device from a first circumference to a second circumference comprises said corrugated sections; and wherein said means associated with said annular ring

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implantable device for maintaining said ring implantable device in said first circumference and, upon said annular ring implantable device being adjusted to said second circumference, for maintaining said annular ring implantable device in said second circumference comprises said corrugated sections being sufficiently stiff that once said annular ring implantable device is placed in a given configuration, it will tend to remain in said given configuration when acted upon by normal anatomic forces at said selected anatomic orifice or lumen.

- 14. (currently amended) The implantable device of claim 1, wherein said annular ring implantable device comprises includes a hollow tube formed into an annular shape, said tube having interspaced smooth and corrugated sections disposed around its circumference, wherein said means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises said tube having portions of narrowed circumference such that a suture can be passed around said tube at said portions of narrowed circumference and hence through the underlying tissue; wherein said means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference comprises said corrugated sections; and wherein said means associated with said annular ring for maintaining said ring in said first circumference and, upon said annular ring being adjusted to said second circumference, for maintaining said annular ring in said second-circumference comprises said corrugated sections being sufficiently stiff that once said annular ring is placed in a given configuration, it will tend to remain in said given configuration when acted upon by normal anatomic forces at said selected anatomic orifice or lumen.
- 15. (currently amended) The implantable device of claim 1, wherein said adjustment member means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first-circumference to a second circumference comprises: includes teeth engaged with formed on at least a portion of said annular ring; a gear engaging said teeth of said annular ring; and said gear and said teeth being arranged such that turning said gear effects relative movement

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between a first end of said annular ring and a second end of said annular ring to adjust the circumference of said annular ring from a first circumference to a second circumference.

- 16. (currently amended) The implantable device of claim 15, further comprising: a wheel positioned tangentially to said gear such that said portion of said annular ring implantable device which engages said gear passes between said gear and said wheel.
- 17. (currently amended) The implantable device of claim 15, wherein said gear is mounted in fixed relation to said <u>a</u> second end of said <u>annular ring implantable</u> <u>device</u>, and wherein said teeth are formed adjacent said first end of said annular ring implantable device.
- 18. (currently amended) The implantable device of claim 15, further comprising wherein said adjustment tool includes
- <u>a turning device</u> means for turning said gear from a location remote from said gear, such that to provide that said a circumference of said implant implantable device can be adjusted after closure of surgical incisions and resumption of physiological flow through said orifice or lumen.
- 19. (currently amended) The implantable device of claim 18, wherein said turning device means for turning said gear from a remote location is disengageable from said gear after completion of adjustments.
- 20. (currently amended) The implantable device of claim 1, wherein said adjustment member means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference comprises: includes a worm gear,[[;]] and an engagement device coupled means operatively associated with a first end of said annular ring implantable device for engaging said worm gear such that rotation of said worm gear effects relative

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movement between said <u>a</u> first end of said <u>annular ring implantable device</u> and a second end of said <u>annular ring implantable device</u> to adjust the <u>a</u> circumference of said <u>annular ring implantable device</u> from a first circumference to a second circumference.

- 21. (currently amended) The implantable device of claim 20, wherein said worm gear has a first angled gear head at its driven end, and further comprising includes a shaft in offset relation to said worm gear and having a second angled gear head at a first end thereof, said first and second angled gear heads drivably engaging such to provide that rotation of said shaft drives said worm gear.
- 22. (currently amended) The implantable device of claim 21, further comprising: wherein said adjustment tool includes a tuning device means for turning said shaft from a location remote from said worm gear, such that said and provide for an adjustment of said circumference of said implant can be adjusted implantable device after closure of surgical incisions and resumption of physiological flow through said orifice or lumen.
- 23. (currently amended) The implantable device of claim 22, wherein said shaft and said tuning device means for turning said shaft from a remote location are disengageable from said worm gear after completion of adjustments.
- 24. (new) The implantable device of claim 1, wherein the fastener is integrated with the implantable device.

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